Gold Coast Health Plan℠
A Public Entity

Pharmacy Newsletter

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The Pharmacy Newsletter is published quarterly for the provider community of Gold Coast Health Plan by the Communications Department.

Information in the Pharmacy Newsletter comes from a wide range of medical experts. If you have any questions regarding its content, please contact GCHP's Clinical Programs Pharmacist Lily Yip, at lyip@goldchp.org or 1-805-437-5873.

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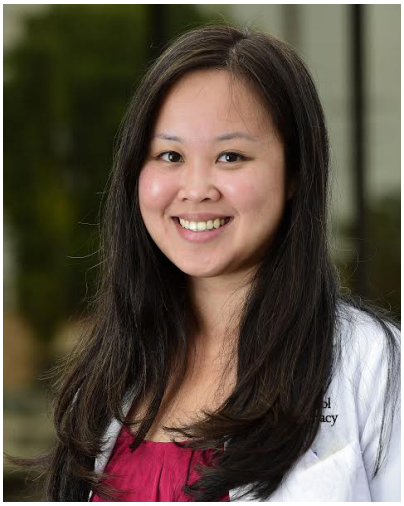
A Message from the Gold Coast Health Plan Clinical Programs Pharmacist



Lily Yip, Pharm.D., APh, CDCES, BCACP

Gold Coast Health Plan's (GCHP) Pharmacy Newsletter is designed to help providers stay current on updates related to the use of medications for GCHP members and to the pharmacy benefit, which is now managed by Medi-Cal Rx.

Our goal is to equip providers with the information necessary to safely prescribe medications and to ensure members have access to all necessary pharmaceutical services through Medi-Cal Rx. We are available to help any members or providers as needed.

We know that you are interested in providing the best care possible to their patients and our members. We value the role you play in the well-being of our community.

If you have any questions, please feel free to contact me at lyip@goldchp.org or 1-805-437-5873.

Sincerely,

Lily Yip, Pharm.D., APh, CDCES, BCACP
Clinical Programs Pharmacist

Medi-Cal Rx Updates

Prior Authorization (PA) Reinstatement

IMPORTANT MESSAGE RELATED TO REINSTATEMENT OF PRIOR AUTHORIZATIONS (PA) AND GRANDFATHERED AUTHORIZATIONS:

Medi-Cal Rx will reinstate PA requirements for the remaining 71 drug classes for new prescriptions in early 2023. Effective Jan. 20, 2023, prior authorization requirements will be reinstated for new starts for 39 drug classes in members 22 years of age and older. The authorizations for the remaining 32 drug classes will go into effect on Feb. 24, 2023. Previously grandfathered prior authorizations for all drug classes will remain in effect through June 22, 2023, after which time a PA will be required for future fills. Please refer to Medi-Cal Rx's Contract Drug List (CDL) to determine which medications will be affected by this change. These changes will not affect patients 21 years of age and younger until a later time. Please look for additional information under Medi-Cal Rx's Bulletins & News as it is released to be sure that you are up to date on the changes.

It is important to note that neither members nor providers will receive prior notification related to any specific grandfathered PA expiring. It is strongly recommended to submit PAs proactively for these medications after Feb. 24, 2023, for any member currently taking medication in the drug classes below to avoid any disruption in therapy.

Reinstatement of PAs in the following drug classes will begin on Jan. 20, 2023:

Therapeutic Class	Therapeutic Class
All Other Dermatologicals	Glucocorticoids
Anabolics	Iodine Therapy
Androgens	Multivitamins
Anesthetic Local Topical	Muscle Relaxants
Antiarthritics	Non-Opioid Analgesics
Antifungals	Ophthalmic Preparations
Antimalarials	Other Antibiotics
Antiparasitics	Other Hormones
Antiparkinson	Penicillins
Anti-Ulcer Preps/Gastrointestinal Preps	Progesterone
Antivirals	Streptomycins
Biologicals	Sulfonamides
Cephalosporins	Systemic Contraceptives
Corticotropins	TB Preparations
Emollients Protectives	Tetracyclines
Erythromycins	Thyroid Preps
Estrogens	Topical Nasal And OTIC Preparations
Fat Soluble Vitamins	Urinary Antibacterials
Folic Acid Preparations	Vitamin K
General Antibacterials and Antiseptics	

General Medi-Cal Rx Information

Effective Jan. 1, 2022, the state Department of Health Care Services (DHCS) carved out all prescription benefits from Managed Care Plans under a program called Medi-Cal Rx. All pharmacy claims should be submitted directly to the state via its pharmacy benefit manager (PBM), Magellan Medicaid Administration, Inc.

For assistance regarding a pharmacy claim or prior authorization, please contact the Medi-Cal Rx Customer Service Center at 1-800-977-2273 or you can send an email at MediCalRxEducationOutreach@magellanhealth.com or chat here. Agents are available 24 hours a day, seven days a week, 365 days per year.

For assistance regarding submitting a PA or appeals for a pharmacy claim to Medi-Cal Rx, please fax 1-800-869-4325.

This information sheet contains all of the important information regarding how to submit a prior authorization or an appeal for a pharmacy claim to Medi-Cal Rx.

You may also visit the Medi-Cal Rx Communication page for any upcoming bulletins and news.

Changes to the Contract Drugs List (CDL) for Medi-Cal Rx

Please check the Medi-Cal Rx Contract Drugs List (CDL) on the Medi-Cal Rx Web Portal for the most recent changes to the prescription and over-the-counter drugs lists. Revisions and/or deletions are made on a monthly basis. Most recent changes made were effective Dec. 1, 2022. Below is a list of the most recent changes to the Contract Drug List for Medi-Cal Rx. Please check the Medi-Cal Rx Contract Drugs List for the most up to date information.

Drug Name	Description	Effective Date
Acalabrutinib	Additional formulation (tablet) added with restriction.	Oct. 1, 2022
Amlodipine Benzoate	Updated age restriction.	Oct. 1, 2022
Baloxavir Marboxil	Updated age restriction.	Oct. 1, 2022
Colestipol Hydrochloride	Additional formulation (tablet) added with restriction.	Oct. 1, 2022
Enalapril Maleate	Updated age restriction.	Oct. 1, 2022
Finerenone	Added to CDL with restriction.	Oct. 1, 2022
Lasmiditan	Updated Code I restriction.	Oct. 1, 2022
Levothyroxine Sodium	Additional formulation (solution) added with restriction.	Oct. 1, 2022
Lisinopril	Updated age restriction.	Oct. 1, 2022
Lorazepam	Removed age restriction.	Oct. 1, 2022
Rimegepant	Updated Code I restriction.	Oct. 1, 2022
Risankizumab-rzaa	Added to CDL with restriction.	Oct. 1, 2022
Ropeginterferon alfa-2b-njft	Updated Code I restriction.	Oct. 1, 2022
Ropinirole HCL	Additional formulation (extended release) added with restriction.	Oct. 1, 2022
Sildenafil Citrate	Updated age restriction.	Oct. 1, 2022
Spironolactone	Updated age restriction.	Oct. 1, 2022
Tranexamic Acid	Added to CDL.	Oct. 1, 2022
Ubrogepant	Updated Code I restriction.	Oct. 1, 2022
Carbidopa	Added to CDL.	Oct. 1, 2022

Drug Name	Description	Effective Date
Chlorpromazine	Additional formulation (liquid) added.	Nov. 1, 2022
Raloxifene	Added to CDL.	Nov. 1, 2022
Sodium Chloride Injection	Additional vial sizes (20 ml and 50 ml) added.	Nov. 1, 2022
Vancomycin	Additional formulations (capsules and solution) added with restrictions.	Nov. 1, 2022
Water for Injection, Sterile Water for Injection, Bacteriostatic	Additional vial sizes (5 ml, 20 ml, 50 ml) added.	Nov. 1, 2022
Aztreonam Lysine	Added to CDL with restriction.	Nov. 1, 2022
Brompheniramine Maleate with Pseudoephedrine HCL and Dextromethorphan	Added to CDL.	Dec. 1, 2022
Cefaclor	Removed Code I restriction.	Dec. 1, 2022
Clindamycin Phosphate	Removed Code I restriction.	Dec. 1, 2022
Dornase Alfa	Added to CDL with restriction.	Dec. 1, 2022
Estradiol Transdermal System Once-Weekly Patch	Additional strengths (0.0375 mg/24 hr, 0.06 mg/24 hr) added.	Dec. 1, 2022
Estradiol Transdermal System Twice-Weekly Patch	Additional strengths (0.025 mg/24 hr, 0.0375 mg/24 hr, 0.05 mg/24 hr, 0.075 mg/24 hr) added.	Dec. 1, 2022
Fluticasone Propionate	Additional formulation (cream) added.	Dec. 1, 2022
Glycopyrrolate	Additional formulation (solution) added.	Dec. 1, 2022
Hydrocortisone Sodium Succinate (PF)	Added to CDL.	Dec. 1, 2022
Ibrutinib	Additional formulation (suspension) added with restrictions.	Dec. 1, 2022
Lacosamide	Added to CDL.	Dec. 1, 2022
Nivolumab	Additional formulation (vial) added with restrictions.	Dec. 1, 2022
Tobramycin	Additional formulation (ampule) added with restriction.	Dec. 1, 2022

Pharmacy Benefit: Blood Pressure Monitors and Cuffs

Blood Pressure Monitors
Effective June 1, 2022, Medi-Cal Rx began covering blood pressure monitors as a pharmacy benefit.

- Members are eligible to receive a new monitor if they have an ICD-10-CM diagnosis code that justifies medical necessity for cardiovascular monitoring for a chronic condition or on a regular basis documented on the prescription for the blood pressure monitor and sent to a pharmacy to bill Medi-Cal Rx.
- One monitor is covered once every five years.
- Covered products are listed on the Medi-Cal Rx website and is frequently updated. Note: Wrist personal blood pressure monitoring devices are not a Medi-Cal Rx benefit.
- Refer to the List of Covered Medical Supplies Product Descriptions and Billing Information for billing and reimbursement information.

Removal of Prior Authorization (PA) Requirement for Covered Blood Pressure Cuffs
Effective Nov. 1, 2022, covered blood pressure cuffs on the List of Covered Personal Blood Pressure Monitoring Devices and Blood Pressure Cuffs will no longer require a PA for coverage. It is now a pharmacy benefit.

- Members are eligible to receive a blood pressure cuff if they have an ICD-10-CM diagnosis code that justifies medical necessity for cardiovascular monitoring for a chronic condition or on a regular basis is required to be documented on the prescription.
- These blood pressure cuffs (large or small) work with covered personal home use blood pressure monitors for use during personal home blood pressure monitoring.
- Covered products continue to be restricted to the List of Covered Personal Blood Pressure Monitoring Devices and Blood Pressure Cuffs. Note: Wrist cuffs are not a Medi-Cal Rx benefit.
- Refer to the List of Covered Medical Supplies Product Descriptions and Billing Information for billing and reimbursement information.

Updates to Continuous Glucose Monitoring Systems

Effective Oct. 1, 2022, both types of continuous glucose monitoring (CGM) systems will be medical supplies pharmacy-billed benefits through Medi-Cal Rx, subject to PA and a contracted List of Covered Continuous Glucose Monitoring Systems. Please refer to the updated List of Covered Continuous Glucose Monitoring (CGM) Systems and the Medi-Cal Rx Provider Manual on the Medi-Cal Rx Web Portal for specific information.

For Fee-for-Service Medi-Cal beneficiaries, beginning Oct. 1, 2022, claims previously paid as a medical benefit billed on a Centers for Medicare & Medicaid Services (CMS) 1500 form via a Healthcare Common Procedure Coding System (HCPCS) must be submitted as a pharmacy claim to Medi-Cal Rx. These HCPCS codes will be denied for medical claims submitted with a date of service after Dec. 1, 2022.

Note: Corresponding insulin pumps for some CGM devices will continue to remain a Durable Medical Equipment (DME) billable as a medical benefit billed on a CMS 1500 form via an HCPCS code. Please refer to the DME section of the Pharmacy Provider Manual on the website for coverage and billing information of DME insulin pumps and accessories.

Diabetic Supplies Updates

Effective Jan. 1, 2023, the Medi-Cal Rx List of Covered Self-Monitoring Blood Glucose Systems (Glucometers), Control Solutions, and Lancing Devices has been updated on the Medi-Cal Rx Web Portal to add LifeScan, Inc. OneTouch® Verio Flex® Meter System; OneTouch Verio Reflect® Meter System; and OneTouch Verio Control Solution as covered blood glucose meters and supplies available as a Medi-Cal Rx benefit.

Find A Pharmacy

To find the nearest pharmacy where prescriptions can be picked up, use this tool. Medi-Cal members can now pick up their prescriptions at Costco Pharmacies. Costco membership is not required to access their pharmacy. Please review the DHCS press release here.

DHCS has a Medi-Cal Rx website that contains the most accurate, up-to-date information. The website includes an overview and background information, frequently asked questions (FAQs), Bulletins & News, Contract Drugs List (CDL), Provider Manual and other helpful information. Please make sure to bookmark this website today and sign up for the Medi-Cal Rx Subscription Services (MCRxSS).

For assistance regarding Medi-Cal Rx, please call the Medi-Cal Rx Customer Service Center at 1-800-977-2273. Agents are available 24 hours a day, seven days a week, 365 days a year.

Please fax PAs regarding pharmacy claims or appeals to Medi-Cal Rx at 1-800-869-4325.

If you need further assistance, please call the GCHP Pharmacy Department at 1-805-437-5738 or email Pharmacy@goldchp.org.

COVID-19 Updates

COVID-19 Information and Resources

Vaccinations
Medi-Cal Rx covers the COVID-19 bivalent vaccines as a pharmacy benefit under the following guidelines:

- Moderna COVID-19 Vaccine: The U.S. Food and Drug Administration (FDA) amended the Emergency Use Authorization (EUA) for the Moderna COVID-19 vaccine to be administered at least two months after primary vaccination or booster dose with any authorized / approved monovalent COVID-19 vaccine in individuals 6 years of age and older as a single booster dose.
- Pfizer-BioNTech COVID-19 Vaccine: The FDA amended the EUA for the Pfizer-BioNTech COVID-19 vaccine to be administered at least two months after primary vaccination or booster dose with any authorized / approved monovalent COVID-19 vaccine in individuals 5 years of age and older as a single booster dose.

For more information, visit:

- Centers for Disease Control and Prevention (CDC): COVID-19 Vaccination Clinical & Professional Resources
- California Department of Public Health (CDPH): COVID-19 Vaccines

COVID-19 Antigen Test Kits

Effective Feb. 1, 2022, Over-the-Counter (OTC) EUA FDA-authorized, self-administered COVID-19 antigen test kits can be billed and reimbursed as a pharmacy-billed medical supply benefit through Medi-Cal Rx in accordance with current Centers for Disease Control and Prevention (CDC) recommendations. Coverage is restricted to specific one-test-per-kit or two-tests-per-kit OTC EUA COVID-19 FDA-authorized, self-administered COVID-19 antigen tests listed in the List of Covered Emergency Use Authorization (EUA) COVID-19 Antigen Tests. This can be found on the Medi-Cal Rx Web Portal under "Forms and Information," and requires dispensing from a pharmacy, written (or electronic equivalent) on a prescription pad signed by a licensed prescriber or a pharmacist. Packages / kits cannot be broken or sold as individual tests.

The following coverage criteria applies:

- Restricted to EUA for the diagnostic condition of suspected COVID-19 (Code I Restriction).
- Restricted to up to eight tests (four kits for two tests / kit) per 30 days per beneficiary.
- No refills allowed. The beneficiary would need to obtain a new prescription for each dispensing. NOTE: Prior authorization (PA) requests for quantities outside the allowed amounts will be denied unless ordered or administered by a provider following an individualized clinical assessment and with appropriate clinical justification provided.

COVID-19 Therapeutics

DHCS reminds Medi-Cal-enrolled providers that COVID-19-related vaccines and therapeutics, including Nirmatrelvir/ritonavir (Paxlovid™) and Molnupiravir (Lagevrio™), are a covered Medi-Cal Rx pharmacy benefit for California residents who do not have insurance or have private insurance that does not cover COVID-19 therapeutics, and who do not qualify for any Medi-Cal programs.

Consider identifying those who are at high risk for severe COVID-19 who may benefit from outpatient COVID-19 treatment if they test positive for COVID-19. Risk factors for severe COVID-19 include:

- Being more than 50 years of age. Risk increases substantially at ≥ 65 years and older.
- Being unvaccinated or not being up to date on COVID-19 vaccinations.
- Specific medical conditions and behaviors.

Important Information About Paxlovid

Paxlovid (nirmatrelvir/PF-07321332 and ritonavir) is an oral antiviral drug that should be initiated as soon as possible after diagnosis of COVID-19 and within five days of symptom onset. Paxlovid is available for patients by prescription only (from a health care provider or through the Test to Treat Program).

Paxlovid is authorized for the treatment of mild to moderate COVID-19 in adult and pediatric patients 12 years of age and older weighing at least 40 kg, with a positive SARS-CoV-2 test, who are at high risk for progressing to severe COVID-19, including hospitalization or death. Please see the Eligibility Screening Checklist for additional details.

Paxlovid is available in two package presentations*:

- Paxlovid Standard Dose: Includes 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet) taken together twice daily for five days. Total of 30 tablets for treatment.
- Paxlovid Renal Dose: For people with moderate renal impairment (eGFR > 30 mL/min to < 60 mL/min) that includes 150 mg nirmatrelvir (one 150 mg tablet) with 100 mg ritonavir (one 100 mg tablet) taken together twice daily for five days. Paxlovid is not recommended for people with severe renal impairment.

** The standard dose pack may be modified for renal dosing. Instructions can be found in the Dispensing Information for Patients with Renal Impairment Document.*

Paxlovid is not authorized for the pre-exposure or post-exposure prevention of COVID-19 or for initiation of treatment in those requiring hospitalization due to severe or critical COVID-19. Paxlovid is not a substitute for vaccination in individuals for whom COVID-19 vaccination and a booster dose are recommended. Also not recommended to be used in patients with severe renal impairment (eGFR<30 mL/min) or in patients with severe hepatic impairment (Child-Pugh Class C). There are known drug interactions with Paxlovid, see the Drug Interaction Checker for more information.

Paxlovid is contraindicated in patients with a history of clinically significant hypersensitivity reactions (e.g., toxic epidermal necrolysis [TEN] or Stevens-Johnson syndrome) to its active ingredients (nirmatrelvir or ritonavir) or any other components of the product. Also contraindicated with drugs that are highly dependent on CYP3A for clearance and for which elevated concentrations are associated with serious and/or life-threatening reactions (e.g., HMG-CoA reductase inhibitors, antiarrhythmics, antipsychotics, etc.).

Paxlovid is also contraindicated with drugs that are potent CYP3A inducers where significantly reduced nirmatrelvir or ritonavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance. Paxlovid cannot be started immediately after discontinuation of any of the following medications due to the delayed offset of the recently discontinued CYP3A inducer (e.g., carbamazepine, phenobarbital, phenytoin, etc.).

Potential side effects from Paxlovid use include dysgeusia (6% and <1%, respectively), diarrhea (3% and 2%), hypertension (1% and <1%), and myalgia (1% and <1%).

In clinical trials, Paxlovid reduced risk of hospitalization or death by 89% (within three days of symptom onset) and 88% (within five days of symptom onset) compared to placebo; no deaths compared to placebo in non-hospitalized, high-risk adults with COVID-19.

Among U.S. adults diagnosed with COVID-19, including those with previous infection or vaccination, persons who were prescribed Paxlovid within five days of diagnosis had a 51% lower hospitalization rate within 30 days after diagnosis than those who were not prescribed Paxlovid.

Please refer to FDA Fact Sheet on Paxlovid for more detailed information.

Important Information About Lagevrio

Lagevrio (molnupiravir, MK-4482) is authorized for the treatment of mild to moderate COVID-19 in adults 18 years of age and older, who are at high risk for progressing to severe COVID-19 and for whom alternative COVID-19 treatment options are not accessible or clinically appropriate. Lagevrio is an oral antiviral drug that is available by prescription only and should be initiated as soon as possible after diagnosis of COVID-19 and within five days of symptom onset.

Lagevrio is not authorized for use in patients less than 18 years of age, for use for longer than five consecutive days, for the pre-exposure or post-exposure prevention of COVID-19 or for initiation of treatment in those requiring hospitalization due to severe or critical COVID-19.

The standard dose for Lagevrio includes 800mg (four 200mg capsules) taken by mouth twice daily (every 12 hours) for five days with or without food. The capsules should be swallowed whole. Don't open or crush the capsules. Total of 40 capsules for treatment.

No contraindications have been identified based on the limited available data. No dosage adjustment is recommended based on renal or hepatic impairment or in geriatric patients.

Lagevrio may cause fetal harm when administered to pregnant individuals. There are no available human data on the use of Lagevrio in pregnant individuals to evaluate the risk of major birth defects, miscarriage or adverse maternal or fetal outcomes; therefore, Lagevrio is not recommended for use during pregnancy. When considering Lagevrio for a pregnant individual, the prescribing health care provider must communicate the known and potential benefits and the potential risks of using Lagevrio during pregnancy to the pregnant individual. Lagevrio is authorized to be prescribed to a pregnant individual only after the health care provider has determined that the benefits would outweigh the risks for that individual patient. If the decision is made to use Lagevrio during pregnancy, the prescribing health care provider must document that the known and potential benefits and the potential risks of using Lagevrio during pregnancy were communicated to the pregnant individual.

Advise individuals of childbearing potential of the potential risk to a fetus and to use an effective method of contraception correctly and consistently, as applicable, during treatment with Lagevrio and for four days after the final dose. Potential side effects from Lagevrio include diarrhea (2%), nausea (1%), dizziness (1%).

In clinical trials, molnupiravir lowered the risk of COVID-19 hospital stays or death by about 30% in high-risk people. This difference in effectiveness may be one of the reasons the FDA suggests using molnupiravir only if other treatments aren't available.

Please refer to FDA Fact Sheet on Lagevrio for more information.

Resources for additional information regarding COVID-19 Therapeutics

- U.S. Department of Health & Human Services Administration for Strategic Preparedness & Response: COVID-19 Therapeutics
- NIH COVID-19 Treatment Guidelines
- Centers for Disease Control and Prevention: Interim Clinical Considerations for COVID-19 Treatment in Outpatients
- California Department of Public Health (CDPH): COVID-19 Treatments
- FDA Fact Sheet on Paxlovid
- NIH COVID-19 Treatment Guidelines: Drug-Drug Interactions Between Ritonavir-Boosted Nirmatrelvir (Paxlovid) and Concomitant Medications
- FDA Fact Sheet on Lagevrio
- U.S. Food and Drug Administration (FDA): Emergency Use Authorization

FDA Alerts

FDA New Drug Approvals

This information is a list of new drugs approved by the FDA. This is only a subset of all drugs that were approved and include all first-time approvals and any other significant drug approvals. Click here to access the FDA's website.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
DROSPIRENONE	*Drospirenone*	Chewable tablet	Indicated for use by females of bleeding or amenorrhea persists. Reproductive potential to prevent pregnancy.
ZONISADE	*Zonisamide*	Oral suspension	Indicated as adjunctive therapy for the treatment of partialonset seizures in adults and pediatric patients 16 years of age and older.
LUMRYZ	*Sodium oxybate*	Oral suspension	Indicated for adults with Narcolepsy.
ZORYVE	*Roflumilast*	Topical cream	Indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older.
CIMERLI	*Ranibizumab-eqrn*	Injectable	Indicated for the treatment of patients with: • Neovascular (wet) age-related macular degeneration (AMD). • Macular edema following retinal vein occlusion (RVO). • Diabetic macular edema (DME). • Diabetic retinopathy (DR). • Myopic choroidal neovascularization (MCNV).
CALQUENCE	*Acalabrutinib maleate*	Oral tablet	Indicated for the treatment of adult patients with: • Mantle cell lymphoma (MCL) who have received at least one prior therapy. This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. • Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).
MIDAZOLAM HYDROCHLORIDE (AUTOINJECTOR)	*Midazolam hydrochloride*	Intramuscular solution	Indicated for the treatment of status epilepticus in adults.
EPINEPHRINE	*Epinephrine*	Intravenous solution	Indicated to increase mean arterial blood pressure in adult patients with hypotension associated with septic shock.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
AUVELITY	*Bupropion hydrochloride; dextromethorphan hydrobromide*	Oral extended-release tablet	Indicated for the treatment of major depressive disorder (MDD) in adults.
IMBRUVICA	*Ibrutinib*	Oral suspension	Indicated for the treatment of: • Adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). • Adult patients with chronic lymphocytic leukemia (CLL) / Small lymphocytic lymphoma (SLL). • Adult patients with chronic lymphocytic leukemia (CLL) / Small lymphocytic lymphoma (SLL) with 17p deletion. • Adult patients with Waldenstrm's macroglobulinemia (WM). • Adult patients with marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy. This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). • Adult and pediatric patients 1 year of age and older with chronic graft versus host disease (CGVHD) after failure of one or more lines of systemic therapy.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
IMBRUVICA	*Ibrutinib*	Oral tablet	Indicated for the treatment of: • Adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). • Adult patients with chronic lymphocytic leukemia (CLL) / Small lymphocytic lymphoma (SLL). • Adult patients with chronic lymphocytic leukemia (CLL) / Small lymphocytic lymphoma (SLL) with 17p deletion. • Adult patients with Waldenstrm's macroglobulinemia (WM). • Adult patients with marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy. This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). • Adult and pediatric patients 1 year of age and older with chronic graft versus host disease (CGVHD) after failure of one or more lines of systemic therapy.
DIAZEPAM	*Diazepam*	Buccal film	It can treat anxiety, muscle spasms, and seizures.
KONVOMEP	*Omeprazole; sodium bicarbonate*	Oral suspension	Indicated in adults for: • Treatment of active benign gastric ulcer. • Reduction of risk of upper gastrointestinal (GI) bleeding in critically ill patients.
XENPOZYME	*Olipudase alfa-rpcp*	Injectable	Indicated for treatment of non-central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients.
STIMUFEND	*Pegfilgrastim-fpgk*	Injectable solution	Indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
SPEVIGO	*Spesolimab-sbzo*	Intravenous injectable	Indicated for the treatment of generalized pustular psoriasis flares in adults.
DAXXIFY	*Daxibotulinumtoxina-lanm*	Injectable	Indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients.
SOTYKTU	*Deucravacitinib*	Oral tablet	Indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
ROLVEDON	*Eflapegrastim-xnst*	Subcutaneous injectable	Indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia. Limitations of use ROLVEDON is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.
TERLIVAZ	*Terlipressin acetate*	Intravenous powder	Indicated to improve kidney function in adults with hepatorenal syndrome with rapid reduction in kidney function. Limitation of use: • Patients with a serum creatinine >5 mg/dl are unlikely to experience benefit.
NOREPINEPHRINE BITARTRATE IN 0.9% SODIUM CHLORIDE	*Norepinephrine bitartrate*	Intravenous solution	Indicated for restoration of blood pressure in adult patients with acute hypotensive states.
APONVIE	*Aprepitant*	Intravenous emulsion	Indicated for the prevention of postoperative nausea and vomiting (PONV) in adults. Limitations of use: • APONVIE has not been studied for the treatment of established nausea and vomiting.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
PEDMARK	*Sodium thiosulfate*	Intravenous solution	Indicated to reduce the risk of ototoxicity associated with cisplatin in pediatric patients 1 month of age and older with localized, non-metastatic solid tumors. Limitations of use: • The safety and efficacy of pedmark have not been established when administered following cisplatin infusions longer than six hours. • Pedmark may not reduce the risk of ototoxicity when administered following longer cisplatin infusions, because irreversible ototoxicity may have already occurred.
ELUCIREM	*Gadopiclenol*	Intravenous solution	
OMLONTI	*Omidenepag isopropyl*	Ophthalmic solution	Indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.
IHEEZO	*Chloroprocaine hydrochloride*	Ophthalmic gel	Indicated for ocular surface anesthesia.
VEGZELMA	*Bevacizumab-adcd*	Injectable	Indicated for the treatment of: • Metastatic colorectal cancer, in combination with intravenous fluorouracilbased chemotherapy for first- or second-line treatment. • Metastatic colorectal cancer, in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line bevacizumab product-containing regimen.
RELYVRIO	*Sodium phenylbutyrate; taurursodiol*	Oral suspension	Indicated for the treatment of lateral sclerosis (ALS) in adults.
LYTGOBI	*Futibatinib*	Oral tablet	Indicated for the treatment of adult patients with previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements. This indication is approved under accelerated approval based on overall response rate and duration of response.
ALVAIZ	*Eltrombopag choline*	Oral tablet	

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
NOREPINEPHRINE BITARTRATE IN 0.9% SODIUM CHLORIDE	*Norepinephrine bitartrate*	Intravenous solution	To raise blood pressure in adult patients with severe, acute hypotension.
FUROSCIX	*Furosemide*	Subcutaneous solution	Indicated for the treatment of congestion due to fluid overload in adults with NYHA Class II/III chronic heart failure.
CEFAZOLIN SODIUM	*Cefazolin sodium*	Intravenous powder	Indicated for: • Treatment of the following infections caused by susceptible isolates of the designated microorganisms in adult and pediatric patients 1 month of age and older for whom appropriate dosing with this formulation can be achieved: ‣ Respiratory tract infections ‣ Urinary tract infections ‣ Skin and skin structure infections ‣ Biliary tract infections ‣ Bone and joint infections ‣ Genital infections ‣ Septicemia ‣ Endocarditis • Perioperative prophylaxis in adult patients. To reduce the development of drug-resistant bacteria and maintain the effectiveness of CEFAZOLIN for injection and other antibacterial drugs, CEFAZALIN for injection should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.
IMJUDO	*Tremelimumab-actl*	Intravenous injectable	Indicated in combination with durvalumab, for the treatment of adult patients with unresectable hepatocellular carcinoma (uhcc).
TECVAYLI	*Teclistamab-cqyv*	Injectable	Indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
IMJUDO	*Tremelimumab-actl*	Injectable	Indicated: • In combination with durvalumab, for the treatment of adult patients with unresectable hepatocellular carcinoma (uhcc). • In combination with durvalumab and platinum-based chemotherapy for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with no sensitizing epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.
ELAHERE	*Mirvetuximab soravtansine-gynx*	Injectable	Indicated for the treatment of adult patients with frα positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Select patients for therapy based on an FDA-approved test.
SEZABY	*Phenobarbital sodium*	Intravenous powder	For the treatment of neonatal seizures in term and preterm infants.
TZIELD	*Teplizumab-mzwv*	Injectable	Indicated to delay the onset of Stage 3 type 1 diabetes (T1D) in adults and pediatric patients aged 8 years of age and older with Stage 2 T1D.

FDA Safety Labeling Changes

This section includes new safety labeling changes or updated boxed warnings or contraindications. Click here to access this information on the FDA's website.

Drug	Type of Change	Change
ULTOMIRIS *(ravulizumab-cwvz)*	Boxed Warning	Because of the risk of serious meningococcal infections, ULTOMIRIS is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called ULTOMIRIS REMS.
ANECTINE *(succinylcholine chloride)*	Contraindications	ANECTINE is contraindicated in patients with: • Known or suspected genetic susceptibility to malignant hyperthermia. • Skeletal muscle myopathies. • Known hypersensitivity to succinylcholine. • After the acute phase of injury following major burns, multiple trauma, extensive denervation of the skeletal muscle, or upper neuron injury because succinylcholine administered to such individuals may result in severe hyperkalemia, which may result in cardiac arrest.
ANORO ELLIPTA *(umeclidinium bromide; vilanterol trifenatate)*	Contraindications	ANORO ELLIPTA is contraindicated in: • Patients with severe hypersensitivity to milk proteins or who have demonstrated hypersensitivity to umeclidinium, vilanterol, or any of the excipients. • Use of a long-acting beta2-adrenergic agonist (LABA), including vilanterol, one of the active ingredients in ANORO ELLIPTA, without an inhaled corticosteroid (ICS), in patients with asthma. ANORO ELLIPTA is not indicated for the treatment of asthma.
DATSCAN *(ioflupane i-123)*	Contraindications	DATSCAN is contraindicated in patients with known serious hypersensitivity to ioflupane I 123.
LILETTA *(levonorgestrel)*	Contraindications	LILETTA is contraindicated when one or more of the following conditions exist: • Pregnancy. • For use as post-coital contraception (emergency contraception). • Congenital or acquired uterine anomaly, including fibroids, that distorts the uterine cavity and would be incompatible with correct IUS placement. • Acute pelvic inflammatory disease (PID) • Postpartum endometritis or infected abortion in the past three months.
LIVALO *(pitavastatin calcium)*	Contraindications	LIVALO is contraindicated in the following conditions: • Concomitant use of cyclosporine. • Acute liver failure or decompensated cirrhosis. • Hypersensitivity to pitavastatin or any inactive excipients in LIVALO. Hypersensitivity reactions including angioedema, rash, pruritus, and urticaria have been reported with LIVALO.

Drug	Type of Change	Change
MARCAINE *(bupivacaine hydrochloride)*	Contraindications	MARCAINE SPINAL is contraindicated in: • Intravenous regional anesthesia (Bier Block). • Patients with septicemia. • Patients with severe hemorrhage, severe hypotension or shock, due to a reduced cardiac output. • Patients with clinically significant arrhythmias, such as complete heart block, due a reduced cardiac output. • Patients with a known hypersensitivity to bupivacaine or to any local anesthetic agent of the amide-type or to other components of MARCAINE SPINAL. • Patients with local infection at the site of proposed lumbar puncture.
QUELICIN *(succinylcholine chloride)*	Contraindications	QUELICIN is contraindicated: • In patients with skeletal muscle myopathies. • In patients with known hypersensitivity to succinylcholine. • In patients with known or suspected genetic susceptibility to malignant hyperthermia.
SKYTROFA *(lonapegsomatropin-tcgd)*	Contraindications	SKYTROFA is contraindicated in patients with: • Acute critical illness after open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure due to the risk of increased mortality with use of pharmacologic doses of somatropin. • Hypersensitivity to somatropin or any of the excipients in SKYTROFA. Severe systemic hypersensitivity reactions, including anaphylactic reactions and angioedema, have been reported.
STENDRA *(avanafil)*	Contraindications	Concomitant Guanylate Cyclase (GC) Stimulators • Do not use STENDRA in patients who are using a GC stimulator, such as riociguat or vericiguat. PDE5 inhibitors, including STENDRA may potentiate the hypotensive effects of GC stimulators.
SUCCINYLCHOLINE CHLORIDE *(succinylcholine chloride)*	Contraindications	Succinylcholine Chloride injection is contraindicated: • In patients with skeletal muscle myopathies. • In patients with known hypersensitivity to succinylcholine. Severe anaphylactic reactions to succinylcholine have been reported. • After the acute phase of injury following major burns, multiple trauma, extensive denervation of skeletal muscle, or upper motor neuron injury, which may result in severe hyperkalemia and cardiac arrest. • In patients with known or suspected genetic susceptibility to malignant hyperthermia.
ULTANE (sevoflurane)	Contraindications	• Known or suspected genetic susceptibility to malignant hyperthermia. • Known or suspected sensitivity to sevoflurane or to other halogenated inhalational anesthetics.
XERMELO (telotristat etiprate)	Contraindications	XERMELO is contraindicated in patients with a history of a hypersensitivity reaction to telotristat. Reactions have included angioedema, rash and pruritis.

Drug Shortages

This section documents drug shortages that were updated in the past 30 days that affect the prescription benefit for GCHP. Click here to access this information on the ASHP Resource Center's website.

Drug Product	Affected Manufacturers	Summary
Ibuprofen Oral Suspension	Teva Taro	• Teva did not provide a reason for the shortage. • Taro was not available to provide information.
Xifaxan oral tablet 200 mg	Bausch Health	Bausch Health has Xifaxan 200 mg tablets on long-term back order and the company cannot estimate a release date.
Dicloxacillin Sodium Capsules oral capsule 250 mg and 500 mg o	Sandoz Teva	• Sandoz discontinued dicloxacillin sodium capsules in January 2022. • Teva did not provide a reason for the shortage. **Estimated Resupply Dates:** • Teva has dicloxacillin sodium 250 mg and 500 mg capsules on back order and the company estimates a release date of late-November 2022.
Albuterol Sulfate inhalation solution 0.5% 2.5 mg/0.5 mL, Unit-of-use vial	Akorn Nephron	• Akorn did not provide a reason for the shortage. • Nephron Pharmaceuticals did not provide a reason for the shortage. **Estimated Resupply Dates:** • Akorn has albuterol sulfate 0.5% inhalation solution on back order and the company estimates a release date in first quarter 2023. • Nephron has albuterol sulfate 0.5% inhalation solution on back order and the company estimates a release date in mid-December 2022.

FDA Drug Safety Communications

This section includes drug alerts that were released in the last three months by the FDA that affect the prescription benefit for GCHP. Click here to access this information on the FDA's website.

Drug	Communications Summary
Prolia *(denosumab)*	The U.S. Food and Drug Administration (FDA) is investigating the risk of severe hypocalcemia with serious outcomes, including hospitalization and death, in patients with advanced kidney disease on dialysis treated with the osteoporosis medicine Prolia (denosumab). The FDA's review of interim results from an ongoing safety study of Prolia suggests an increased risk of hypocalcemia, or low calcium levels in the blood, in patients with advanced kidney disease. Preliminary results from a separate internal FDA study further investigating hypocalcemia in dialysis patients treated with Prolia show a substantial risk with serious outcomes, including hospitalization and death.

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A Public Entity

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For additional information, contact the
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